# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

STEPHANIE CRUM, and GLENN CRUM,	)	
Plaintiffs,	)	
v.	)	Case No. 1:20-cv-00570-TWP-DML
AMERICAN MEDICAL SYSTEMS, INC.,	)	
Defendant.	)	

#### ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

This matter is before the Court on a Motion for Summary Judgment filed pursuant to Federal Rule of Civil Procedure 56 by Defendant American Medical Systems, Inc. ("AMS") (Filing No. 74). Plaintiffs Stephanie Crum ("Crum") and Glenn Crum ("Mr. Crum") (collectively, "Plaintiffs") filed this lawsuit after suffering personal injury because of the erosion of pelvic mesh that had been implanted in Crum. AMS filed a Motion for Summary Judgment, asserting that the Plaintiffs untimely filed their action after the statute of limitations had expired. For the following reasons, the Court **grants** AMS's Motion.

### I. PROCEDURAL BACKGROUND

This action is one of thousands of cases from around the country that brings numerous claims against multiple pharmaceutical companies regarding their pelvic mesh products. This case originally was filed in 2013 in the United States District Court for the Southern District of West Virginia for coordinated and consolidated pretrial proceedings with other pelvic mesh cases. Judge Joseph R. Goodwin presided over the multidistrict litigation ("MDL"), *In re: American Medical Systems, Inc., Pelvic Repair Systems Products Liability Litigation*, MDL number 2325, master file number 2:12-md-02325. On February 6, 2020, Judge Goodwin issued a transfer order, which

directed the transfer of thirty-nine pending cases to the United States district courts that were considered the proper venue for each case. This action is one of the thirty-nine cases identified in the transfer order and was transferred to this Court on February 20, 2020. Prior to transfer, the necessary fact witness depositions and discovery were completed and AMS filed two motions for summary judgment (Filing No. 49; Filing No. 51; Filing No. 31; Filing No. 33).

The Plaintiffs filed a "Short Form Complaint" in the MDL case and noted their claims against AMS were for negligence, strict liability design defect, strict liability manufacturing defect, strict liability failure to warn, breach of express warranty, breach of implied warranty, fraudulent concealment, constructive fraud, discovery rule tolling and fraudulent concealment, negligent misrepresentation, negligent infliction of emotional distress, violation of consumer protection laws, gross negligence, unjust enrichment, loss of consortium, and punitive damages (Filing No. 1 at 4–5). As ordered by this Court, after the case was transferred to the Southern District of Indiana, AMS refiled its summary judgment motions (Filing No. 71; Filing No. 74), and the Court heard oral argument from the parties on the Motions on December 10, 2020 (Filing No. 106).

## II. <u>FACTUAL BACKGROUND</u>

The following facts are not necessarily objectively true, but as required by Federal Rule of Civil Procedure 56, the facts are presented in the light most favorable to the Plaintiffs as the non-moving party. *See Zerante v. DeLuca*, 555 F.3d 582, 584 (7th Cir. 2009); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

On January 15, 2009, Crum was implanted with an AMS SPARC mid-urethral sling to treat her stress urinary incontinence. This procedure was performed by urologist William Shirrell ("Dr. Shirrell") at the St. Vincent Hospital in Carmel, Indiana. When Crum visited her OB/GYN for a routine annual gynecological examination on September 21, 2009, her OB/GYN observed

mesh eroding through her vagina and recommended that Crum follow up with her urologist (Filing No. 75-7 at 2; Filing No. 75-1 at 2, 6). Crum called Dr. Shirrell that same day and left a message stating that "she had seen her GYN recently . . . and her GYN [could] see some material eroding through the vaginal wall and feels it might be her SPARC." (Filing No. 75-2 at 2.) Crum asked for an appointment with Dr. Shirrell, and an appointment was made. *Id*.

On September 30, 2009, Crum met with Dr. Shirrell who advised Crum that she had eroded mesh into the vagina from the SPARC sling (Filing No. 75-3 at 5). Dr. Shirrell noted that "it look[ed] like she [had] unzipped a portion of her anterior vaginal wall that overlay the foreign body, and this [was] readily palpable vaginally." *Id.* at 4. Crum complained that she was experiencing bladder spasms, painful intercourse, the urge to urinate, vaginal pain, vaginal bleeding, daily discomfort, and pressure on the rectum (Filing No. 75-4 at 5-7). Crum later testified,

[W]hen I went in 2009 and I had the surgery and I went back and [Dr. Shirrell] told me I wasn't healing right, I said, something feels wrong. So I would say it was after the surgery, and then things were not right down there. And I knew that, that they weren't.

*Id.* at 12.

During that time period Crum believed that she was not healing properly (Filing No. 96-2 at 9–10). Dr. Shirrell also believed that something had gone wrong in the healing process, but he could not say definitively whether it was a separation of the initial incision or the extrusion of the graft. Dr. Shirrell wanted to first try a conservative treatment with estrogen cream, hoping that the estrogen cream would stimulate her vaginal tissue and promote healing. Dr. Shirrell explained that if the estrogen cream did not promote tissue growth to cover the eroding graft, then surgery would be necessary to either cover the graft or excise a piece of the graft (Filing No. 96-1 at 13, 26–27).

Crum returned to Dr. Shirrell on October 28, 2009, to evaluate how the estrogen therapy was progressing. Dr. Shirrell told Crum that they would have to surgically cover the exposed mesh with a flap or excise the exposed mesh. *Id.* at 13–14. On November 16, 2009, Dr. Shirrell performed mesh revision surgery to address Crum's mesh erosion. A section of the mesh was removed because it was exposed in Crum's vagina. Crum signed a surgical consent form that confirmed she received an "excision of eroded graft material from SPARC surgery." (Filing No. 75-5 at 2; Filing No. 75-7 at 3.) It took Dr. Shirrell eight minutes to perform this surgery to remove the three millimeter portion of exposed mesh (Filing No. 96-1 at 14–15).

At her December 9, 2009, post-operative follow-up appointment, Crum complained to Dr. Shirrell of ongoing discomfort and a poking/pulling sensation in the vaginal area. Dr. Shirrell believed the discomfort and pulling sensation were from having surgery in the area, and he planned to just let the healing process continue. *Id.* at 15; Filing No. 75-4 at 10–11. At her next post-operative follow-up appointment on January 6, 2010, Crum complained of a pulling sensation with certain motions as well as a deep discomfort. Dr. Shirrell believed this was a result of scar tissue along one arm or the other of her graft (Filing No. 96-1 at 27).

Throughout 2011, Crum returned to Dr. Shirrell with complaints of infection, suprapubic pain, urgency, and frequency. Dr. Shirrell never indicated that these symptoms were being caused by the SPARC, and he specifically noted on September 29, 2011, that he did not believe the graft was the source of Crum's pain. *Id.* at 16–18, 27–28.

Crum again returned to Dr. Shirrell on June 21, 2012, and during this visit, Dr. Shirrell found erosion of the graft into Crum's vagina. The vaginal examination was extremely painful and very uncomfortable. The following week, on June 25, 2012, Dr. Shirrell performed a second mesh revision surgery to remove the eroding graft. This procedure took five minutes, and there were no

complications (<u>Filing No. 96-1 at 19</u>–20; <u>Filing No. 96-2 at 33</u>; <u>Filing No. 76-2 at 2</u>). In 2013, Crum stopped treating with Dr. Shirrell because she was content to manage her symptoms on her own (<u>Filing No. 96-2 at 11</u>).

At some point in 2013, Mr. Crum saw a television advertisement about vaginal mesh litigation and pointed it out to Crum. After seeing this advertising, Crum began inquiring with attorneys to see if she had a case. On July 3, 2013, pursuant to MDL Pretrial Order 66, Plaintiffs' counsel emailed a Short Form Complaint, Notice of a Lawsuit, Request to Waive Service of a Summons, and implant records to AMS. Then on December 27, 2013, Plaintiffs' counsel formally filed the Short Form Complaint in federal court (Filing No. 96-2 at 5-6; Filing No. 96-3 at 2-3; Filing No. 1).

Concerning her claim information, Crum explained that she consented to the mesh revision surgeries on November 16, 2009, and June 25, 2012, because she was "experiencing vaginal erosion, bladder spasms, pain with intercourse, vaginal bleeding, pulling/poking sensation, urge to urinate frequently, rectal spasms, and discomfort." (Filing No. 75-7 at 3.) She further explained that she is claiming bodily injury from AMS's SPARC because she "suffered from pulling/poking sensation, no longer able to have intercourse due to pain, urge to urinate frequently, bladder spasms, vaginal grafts." *Id*.

## III. SUMMARY JUDGMENT STANDARD

The purpose of summary judgment is to "pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Federal Rule of Civil Procedure 56 provides that summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material

fact and that the moving party is entitled to a judgment as a matter of law." *Hemsworth v. Quotesmith.com, Inc.*, 476 F.3d 487, 489–90 (7th Cir. 2007). In ruling on a motion for summary judgment, the court reviews "the record in the light most favorable to the non-moving party and draw[s] all reasonable inferences in that party's favor." *Zerante*, 555 F.3d at 584 (citation omitted). "However, inferences that are supported by only speculation or conjecture will not defeat a summary judgment motion." *Dorsey v. Morgan Stanley*, 507 F.3d 624, 627 (7th Cir. 2007) (citation and quotation marks omitted). Additionally, "[a] party who bears the burden of proof on a particular issue may not rest on its pleadings, but must affirmatively demonstrate, by specific factual allegations, that there is a genuine issue of material fact that requires trial." *Hemsworth*, 476 F.3d at 490 (citation omitted). "The opposing party cannot meet this burden with conclusory statements or speculation but only with appropriate citations to relevant admissible evidence." *Sink v. Knox County Hosp.*, 900 F. Supp. 1065, 1072 (S.D. Ind. 1995) (citations omitted).

"In much the same way that a court is not required to scour the record in search of evidence to defeat a motion for summary judgment, nor is it permitted to conduct a paper trial on the merits of [the] claim." *Ritchie v. Glidden Co.*, 242 F.3d 713, 723 (7th Cir. 2001) (citations and quotation marks omitted). "[N]either the mere existence of some alleged factual dispute between the parties nor the existence of some metaphysical doubt as to the material facts is sufficient to defeat a motion for summary judgment." *Chiaramonte v. Fashion Bed Grp., Inc.*, 129 F.3d 391, 395 (7th Cir. 1997) (citations and quotation marks omitted).

#### IV. <u>DISCUSSION</u>

Indiana applies a two-year statute of limitations to personal injury actions. *See* Ind. Code § 34-20-3-1 ("product liability action in which the theory of liability is negligence or strict liability in tort . . . must be commenced . . . within two (2) years after the cause of action accrues"); *Kozmer* 

v. Bayer Healthcare Pharm. Inc., 2007 WL 4148003 (N.D. Ind. Nov. 19, 2007). The general rule is that a cause of action "accrues" when "the plaintiff knew or should have discovered that she suffered an injury or impingement, and that it was caused by the product or act of another." Degussa Corp. v. Mullens, 744 N.E.2d 407, 410 (Ind. 2001).

AMS asks the Court to enter summary judgment in its favor and dismiss the Plaintiffs' action based on Indiana's two-year statute of limitations because Crum began experiencing the symptoms of which she complains in this lawsuit almost immediately after her implant in January 2009 and in her "Plaintiff Fact Sheet," Crum complained of six of the eight symptoms in 2009, which she claims as injuries in her 2013 lawsuit. Crum had revision surgery on November 16, 2009, to treat those same alleged injuries. Thus, AMS argues, by November 16, 2009, Crum attributed her symptoms to her AMS SPARC device. Yet, Crum did not file her lawsuit until December 27, 2013, more than four years later. Thus, under Indiana's two-year statute of limitations, Crum's claims against AMS are time-barred.

AMS has designated evidence to show that Crum was implanted with an AMS SPARC mid-urethral sling on January 15, 2009, to treat her stress urinary incontinence. On September 21, 2009, when Crum saw her OB/GYN for her annual examination, her physician observed mesh eroding through her vagina. Her OB/GYN recommended that she follow up with her urologist. That same day, Crum called Dr. Shirrell, the urologist who had implanted the SPARC, and left a message explaining that she had seen her OB/GYN recently, and her OB/GYN could see some material eroding through the vaginal wall. Crum explained it felt like it might be her SPARC. Dr. Shirrell confirmed Crum's mesh exposure and told Crum about it on September 30, 2009. At that same visit, Crum complained that she was experiencing bladder spasms, painful intercourse, the

urge to urinate, vaginal bleeding, and daily discomfort, which she later described as a pulling sensation, and she told Dr. Shirrell that something was not right in her vaginal area.

On November 16, 2019, Dr. Shirrell performed mesh revision surgery to address Crum's mesh erosion. Crum signed a consent form which confirmed that she received an excision of eroded graft material from her SPARC surgery. A section of mesh was removed because it was exposed in her vagina. However, Crum's symptoms did not go away after the revision surgery. At her post-op visit with Dr. Shirrell a few weeks later, Crum complained again of a pulling sensation in her vagina. On January 6, 2010, Dr. Shirrell determined that the pulling sensation with certain motions, of which Crum complained felt like a deep discomfort, was probably scar tissue along one arm of Crum's mesh implant. She continued to suffer the same symptoms over the next two years, and in 2012, Crum experienced another small mesh erosion that was found as a result of her treatment for the same symptoms she had been experiencing since 2009. On June 25, 2012, Dr. Shirrell did a second similar revision surgery, and in 2013, Crum stopped treating with Dr. Shirrell because she wanted to manage her symptoms on her own.

AMS argues that the undisputed evidence demonstrates that Crum knew at the latest by January 6, 2010, that she was injured after she was told her mesh eroded into her vagina, and she reported to her doctor all of the same injuries she complains of today, which she associated with her SPARC implant. Crum was told of her mesh erosion on September 30, 2009. She underwent mesh revision surgery and signed a consent acknowledging that her mesh was being revised on November 16, 2009. On January 6, 2010, Crum reported to Dr. Shirrell all the symptoms she complains of today except the pulling sensation. Thus, AMS argues, Crum's claims accrued in 2009, and by January 6, 2010, at the latest, but she failed to bring her lawsuit before the statute of

limitations had expired, instead waiting until December 2013. Therefore, this action should be dismissed for being untimely filed.

The Plaintiffs agree that Indiana's two-year statute of limitations applies to this action; however, they contend their Complaint was timely filed within the appropriate two-year period. They argue Crum did not know the injuries of which she complained were caused by the product of another—the AMS SPARC—until 2013, thus, their lawsuit should be treated as effectively filed on July 3, 2013, well within the two-year statute of limitations.

The Plaintiffs point out that during Crum's visit with Dr. Shirrell on September 30, 2009, Dr. Shirrell thought something had gone wrong in the healing process but could not tell if it was a separation of the initial incision or an extrusion of the mesh. Crum thought that she was not healing properly. Dr. Shirrell wanted to initially treat the problem conservatively with estrogen cream, hoping that this would promote healing. On October 28, 2009, when Crum returned to Dr. Shirrell, he determined that surgery was necessary. Dr. Shirrell hoped to avoid excising any portion of the graft and to simply help Crum's healing process. Crum understood that the surgery was to help the process.

They note that the November 16, 2009 surgery was a quick procedure where Dr. Shirrell dissected a small portion of exposed mesh and drew tissue over the top of the area to heal. After waking up from this surgery, Crum did not believe the mesh was the cause of her symptoms. When she followed up with Dr. Shirrell on December 9, 2009, she complained of a pulling sensation, which Dr. Shirrell believed was caused by surgery in the area, and she needed to let the healing continue. During her follow-up appointment on January 6, 2010, Crum again complained of the pulling sensation, and Dr. Shirrell thought it was from the dissection along the vaginal walls.

During 2011, Crum continued to see Dr. Shirrell with complaints of various pain, and during a September 29, 2011 visit, Dr. Shirrell opined that Crum's pain was not from the graft.

The Plaintiffs contend that it was not until June 21, 2012, when Crum again visited Dr. Shirrell, that he found erosion of the graft into the vagina. Dr. Shirrell performed a revision surgery on June 25, 2012. Then sometime during 2013, Crum's husband saw an advertisement about vaginal mesh litigation, and they sought out attorneys. On July 3, 2013, pursuant to MDL Pretrial Order 66, the Plaintiffs' attorney forwarded a Short Form Complaint, Notice of Lawsuit, Request to Waive Service of Summons, and implant records to AMS. Then Plaintiffs' counsel formally filed their Complaint on December 27, 2013, being deemed filed July 3, 2013, pursuant to MDL Pretrial Orders 66 and 80.

The Plaintiffs argue there is a dispute between the parties as to when Crum discovered the cause of her injuries, and because there is a dispute as to the proper conclusions to draw when evaluating the facts on this issue, summary judgment must be denied. They assert that a plaintiff must know that they are injured and that the injury is caused by the act or product of another, and AMS's argument requires Crum (who is not medically or legally trained) to self-diagnose the cause of her injury to be the product of another.

Relying on the Indiana Supreme Court decision in *Degussa*, the Plaintiffs' explain that the statute of limitations begins to run once a plaintiff's doctor expressly informs the plaintiff that there is a reasonable possibility, if not a probability, that an injury was caused by an act or product; then the issue may become a matter of law. Like the plaintiff in *Degussa*, Crum was responsible and diligently followed her physician's recommendations and continued to gather information. Crum should be entitled to rely on the expertise of her physician, who specifically indicated that he did

not think the mesh was the source of her pain in 2011. The Plaintiffs argue that Crum's testimony makes it clear she was not aware until 2013 that her SPARC was the cause of her injuries.

The Plaintiffs argue that at no point before her June 21, 2012 appointment with Dr. Shirrell could Crum have discovered, in the exercise of reasonable diligence, that the SPARC was causing her issues. Dr. Shirrell never blamed the SPARC for the 2009 graft exposure. When Crum presented with an exposure in September 2009, Dr. Shirrell testified he did not relate any of Crum's complaints to the SPARC sling. The operation AMS believes triggered the statute of limitations was less than ten minutes in duration, and both Crum and her physician testified to the belief that Crum was merely undergoing delayed healing. As soon as Crum had enough information to begin exploring whether she had the foundation for litigation, she began looking for counsel, and the Plaintiffs filed suit within the statute of limitations.

AMS replies that the Plaintiffs' argument—Crum could not have known her injuries were caused by her mesh implant until 2013 when her husband saw a lawyer's television advertisement for vaginal mesh litigation—is unavailing. Dr. Shirrell told Crum on January 6, 2010, that he thought her vaginal pulling sensation was related to the mesh. And Crum told Dr. Shirrell (not the other way around) that her mesh was exposed in her vagina in September 2009, and at that time, she reported the same symptoms of which she complains today. Thus, AMS argues, Crum had all the information she needed to file a lawsuit at any time within the following two-year period—until January 6, 2012.

AMS asserts that, while the Plaintiffs point out by September 2011 that Dr. Shirrell thought the pulling pain might be due to something else, the Plaintiffs failed to also point out that from 2011 to the present day, Dr. Shirrell did not and does not attribute any of Crum's symptoms to her mesh implant. At no other time did Dr. Shirrell tell Crum that the symptoms of which she

complained were caused by any defect in her SPARC. Additionally, sometime in 2013, while or just before discussing filing a lawsuit with her lawyers, Crum stopped seeing Dr. Shirrell altogether and was managing her symptoms on her own. Since Dr. Shirrell is the only treating physician Crum ever saw relating to her mesh issue prior to filing her Complaint, there was never any definitive medical diagnosis that could restart the running of the statute of limitations. AMS argues the facts strongly support establishing January 6, 2010, as the latest date the statute should have started running. Given Crum's lack of diligence and responsible efforts to discover whether she had been injured by AMS's mesh from 2009 through the filing of her Complaint, including seeking a second opinion, as well as the complete lack of a definitive diagnosis at any time prior to the filing of the Complaint, the Plaintiffs' argument for a delayed discovery of the claims is unavailing.

AMS also argues that the Plaintiffs' contention that the second revision surgery in 2012 started the statute of limitations is faulty. Crum testified that her 2012 vaginal examination was extremely painful, Dr. Shirrell mentioned "there it is" when he identified some extruding mesh, and the 2009 revision surgery was uncomplicated and took only eight minutes. However, AMS asserts, the 2012 revision surgery was the same in symptoms and severity. Crum's 2009 vaginal examination was very uncomfortable, there was eroding, extruding mesh, and the 2012 revision surgery took only five minutes. The evidence does not support starting the statute of limitations clock in 2012 but not in 2009.

AMS asserts that even if the Plaintiffs' Complaint is deemed to be filed on July 3, 2013, it was still filed three and a half years after Crum told her implanting physician that mesh had eroded into her vagina and after she had complained of all the symptoms of which she complains today, including the pulling sensation in her vagina. AMS asserts that the Plaintiffs cannot credibly believe that having a lawyer tell a plaintiff that she has a case starts running a statute of limitations.

AMS's position that the facts of this case bear heavily in favor of their argument that the statute began running in December 2009 or January 2010 is supported by the evidence designated by both AMS and the Plaintiffs. On January 15, 2009, Crum was implanted with the AMS SPARC by Dr. Shirrell. On September 21, 2009, she visited her OB/GYN, who observed mesh eroding through her vagina and recommended that Crum follow up with Dr. Shirrell. Crum called Dr. Shirrell that same day and left a message that her OB/GYN could see some material eroding through the vaginal wall, and she felt like it might be her SPARC.

On September 30, 2009, Crum met with Dr. Shirrell who confirmed that Crum had eroded mesh in her vagina from the SPARC sling. Crum complained that she was experiencing bladder spasms, painful intercourse, the urge to urinate, vaginal pain, vaginal bleeding, daily discomfort, and pressure on the rectum. After trying conservative treatment, on November 16, 2009, Dr. Shirrell performed mesh revision surgery to remove the mesh that was exposed in Crum's vagina, and Crum signed a surgical consent form that confirmed she received an "excision of eroded graft material from SPARC surgery." At her December 9, 2009 post-operative follow-up appointment, Crum complained to Dr. Shirrell of ongoing discomfort and a poking or pulling sensation in the vaginal area, and at her January 6, 2010 appointment, Crum complained of a pulling sensation with certain motions as well as a deep discomfort.

At that point in time, Crum knew or should have discovered that she suffered an injury that was caused by the product another. She had received the AMS product implant, both her OB/GYN and implanting physician informed her that the AMS product was eroding into her vagina, she complained of numerous physical problems in the vaginal area (the same problems she complains of now in this lawsuit), she signed a surgical consent form to receive an excision of eroded graft material from the SPARC surgery, and she continued to complain of discomfort after the

November 2009 revision surgery. The Plaintiffs' claims against AMS accrued by this point in time. Yet, the Plaintiffs waited until July 3, 2013, to initiate their lawsuit against AMS. This is well outside the two-year period for bringing product liability personal injury lawsuits in Indiana. Therefore, AMS is entitled to summary judgment on the Plaintiffs' claims based on the statute of limitations.

## IV. <u>CONCLUSION</u>

For the reasons discussed above, Defendant AMS's Motion for Summary Judgment (<u>Filing No. 74</u>) is **GRANTED**, and the Plaintiffs' claims are **dismissed**. All other pending motions are **denied as moot**. Final judgment will issue under separate order.

#### SO ORDERED.

Date: 1/20/2021

Hon. Tanya Walton Pratt, Judge United States District Court Southern District of Indiana

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<sup>&</sup>lt;sup>1</sup> The Court notes that, from the designated evidence, it appears Dr. Shirrell did not and still does not believe the mesh implant caused Crum's pain, so the fact that he held that opinion on September 29, 2011, does not affect when Crum knew or should have discovered that she suffered an injury that was caused by the product another.

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